Pacifier use and sudden infant death syndrome: results from the CESDI/SUDI case control study

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Abstract

Objectives—To investigate the relation between pacifier use and sudden infant death syndrome (SIDS).

Design—Three year population based, case control study with parental interviews for each death and four age matched controls.

Setting—Five regions in England (population > 17 million).

Subjects—325 infants who had died from SIDS and 1300 control infants.

Results—Significantly fewer SIDS infants (40%) than controls (51%) used a pacifier for the last/reference sleep (univariate odds ratio (OR), 0.62; 95% confidence interval (CI), 0.46 to 0.83) and the difference increased when controlled for other factors (multivariate OR, 0.41; 95% CI, 0.22 to 0.77). However, the proportion of infants who had ever used a pacifier for day (66% SIDS *v* 66% controls) or night sleeps (61% SIDS *v* 61% controls) was identical. The association of a risk for SIDS infants who routinely used a pacifier but did not do so for the last sleep became non-significant when controlled for socio-economic status (bivariate OR, 1.39 (0.93 to 2.07)).

Conclusions—Further epidemiological evidence and physiological studies are needed before pacifier use can be recommended as a measure to reduce the risk of SIDS.

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In general, health care professionals have not encouraged the use of a pacifier ("dummy" or "soother") for infants. We have shown in a prospective cohort study that pacifier use is more prevalent among the more deprived socioeconomic groups, and in families in which one or both parents smoked, and that it is associated with a significantly higher incidence of minor illnesses, particularly respiratory and gastrointestinal infections. The association with illness persisted after taking account of socioeconomic factors and parental smoking, suggesting that it was a feature of pacifier use rather than of the conditions in which such use occurred.[1]

However, three studies, one from New Zealand,[2] one from the Netherlands,[3] and one form Norway,[4] reported that the use of a pacifier might have a protective effect against sudden infant death syndrome (SIDS). Because these findings raise the possibility that there may be a benefit as well as a risk from pacifier use, we investigated this in the study of sudden unexpected deaths in infancy undertaken within the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI/SUDI) study, a large population based, case control study in the UK.

We report the relation between pacifier use and the risk of SIDS, in which we have examined both the effects of routine pacifier use and use specifically for the last sleep.

Methods

The study was conducted in five former NHS regions of England, with a population of 17.7 million. A case control study and confidential inquiry of all sudden unexpected post-perinatal deaths (age 7 to 364 days) was conducted over a three year period from 1993 to 1996. Infants who died were ascertained through a communication network of professionals and lay organisations who reported all sudden unexpected deaths within 24 hours. Data were collected on a standard questionnaire by research interviewers, consistency of approach being maintained by regular training meetings. The interviewers visited each bereaved family twice. On the first occasion, usually within five days of the death, after obtaining informed consent they took a standardised semistructured history, including a narrative account of events leading up to and surrounding the infant's final sleep or death. On the second visit, a few days later and usually within two weeks of the death, they completed the full questionnaire.

Details of the methodology have been reported previously.[5–7] The questionnaire included a total of over 600 fields, including demographic and social data; the medical history of the infant and other family members; use of cigarettes, alcohol, and drugs; the precise sleeping arrangements for the infant; and full details of the events preceding and the circumstances surrounding the death. Information was collected with regard to both the family's usual practices (including pacifier use) by day and by night, the last 24 hours of the infant's life, and the period when the baby died.

Four controls for each case were selected. The health visitor for the infant who died was asked to identify the two babies on her list next older and the two babies next younger, within two weeks of the age of the index baby. If a health visitor did not have four suitable babies on her own list she drew from the list of her

nearest colleague. The interviewer visited each control family within a week of the death to collect the same data as for the index case. A period of sleep (the "reference sleep") was identified in the control infant's life in the 24 hours before the interview corresponding to the time of day during which the index baby had died, particular importance being given to the index parents' view of whether it had been a night or a daytime sleep. Data were collected for this period equivalent to those collected for the index baby.

A potential concern with all such studies is that parents of infants who have died may not give information as accurately as control families—their grief and distress at the death of their baby might mean that they do not give information on factors which they may regard as being undesirable (for example, pacifier use) or risky (for example, sleeping position). Although it is not possible to eliminate the possibility of such bias completely, the data collected from several sources in our study (the parents, the accident and emergency records, the pathologist, and the general practitioner) were remarkably consistent, even for information such as sleeping position, which was widely known to be a risk factor for SIDS at the time of our study. From this and previous studies using similar methodology, in which the parents of victims of SIDS were interviewed soon after the deaths,[5 8 9] we believe that the data collected are accurate and relatively free from recall bias.

CLASSIFICATION OF THE "CAUSE" OF DEATH
A full paediatric postmortem examination was performed on all infants who died suddenly and unexpectedly, according to an agreed protocol. All deaths were reviewed at a multidisciplinary confidential inquiry meeting, at which the cause of death was classified according to the Avon clinicopathological scoring system.[9] Our report deals only with those cases that were classified as SIDS, together with their matched controls. SIDS was defined as the sudden death of an infant, unexpected by history, for which no sufficient explanation was identified by the multidisciplinary panel after a

full paediatric postmortem examination, review of the medical and social history, and assessment of the circumstances of the death.[10]

STATISTICAL METHODS
Testing for trends in the data was conducted using the χ^2 test for proportions. If there was no obvious grouping, equal proportions using appropriate centile cut offs from the whole dataset were taken. Departure from linearity was also tested. Testing for differences within subgroups of particular variables was conducted using the Mantel-Haenszel test. Odds ratios (OR), 95% confidence intervals (CI), and p values were calculated taking into account the matching using the statistical package SAS.[11] The same package was used to conduct conditional logistic regression for the multivariate analysis, using the PHREG procedure to compare each index group with matched controls. Models were constructed using the stepwise method for selection of variables. Because the age distribution of the victims of SIDS and the control infants was slightly different, age was used as a mandatory covariate in all analyses.

Approval for our study was given by the local research ethics committees in each district in which the study was conducted. Informed consent was obtained from all parents of SIDS victims and control infants.

Results
ASCERTAINMENT
During the three year study period a total of 456 sudden unexpected deaths of infants were identified in the study regions. By a comparison with officially collected statistics on infant deaths (Office for National Statistics) we have subsequently identified a total of eight infant deaths in the study regions that met our entry criteria but were not included, mostly because the infants died outside the regions (ascertainment 98.3%). Of these deaths, 363 were attributed by the multidisciplinary panels to SIDS. Our report deals with the results from the 325 victims of SIDS (89.5% of the total) from whom full data were available for the index infant and the four matched controls. Although the age matching between cases and their matched controls was close, the controls were ~ 10 days older than the index infants. This was largely the result of the delays in making contact with the control families. As in the previously published two year study,[8] our three year study showed no significant difference in the numbers of deaths on different days of the week.

ROUTINE PACIFIER USE
There was very little difference in routine pacifier use between victims of SIDS and the control infants (table 1) for either day or night sleeps, as either a multicategorical or dichotomous variable. The proportion of infants who usually used a pacifier at least sometimes by day or night was 68% for both index and control groups (OR, 1.03; 95% CI, 0.77 to 1.38).

Table 2 stratifies the prevalence of routine pacifier use for possible confounders such as

Table 1 Comparison of routine pacifier use by night or day

Night	SIDS		Controls			
	n = 318	%	n = 1299	%	Univariate OR (95% CI)	p Value
Multicategorical						
Never	124	39.0	513	39.5	1.00 (reference group)	
Sometimes	93	29.2	316	24.3	1.14 (0.82 to 1.59)	0.45
Often	24	7.5	130	10.0	0.78 (0.46 to 1.31)	0.35
Always	77	24.2	340	26.2	1.00 (0.70 to 1.43)	0.99
Dichotomous						
Never	124	39.0	513	39.5	1.00 (reference group)	
Ever	194	61.0	786	60.5	1.03 (0.78 to 1.36)	0.86
Day	*n = 318*	*%*	*n = 1298*	*%*		
Multicategorical						
Never	107	33.6	448	34.5	1.00 (reference group)	
Sometimes	118	37.1	416	32.0	1.16 (0.84 to 1.60)	0.37
Often	25	7.9	156	12.0	0.63 (0.37 to 1.05)	0.08
Always	68	21.4	278	21.4	1.09 (0.74 to 1.61)	0.67
Dichotomous						
Never	107	33.6	448	34.5	1.00 (reference group)	
Ever	211	66.4	850	65.5	1.04 (0.78 to 1.38)	0.82

CI, confidence interval; OR, odds ratio.

Table 2   Routine pacifier use stratified by age, socioeconomic status, breast feeding duration, and maternal smoking after pregnancy

	Proportion of infants who had ever used a pacifier (day or night)			
	SIDS		Controls	
*Infant age**	n	%	n	%
0–8 weeks	53/88	60.2	211/292	72.3
9–14 weeks	70/86	81.3	253/356	71.1
15–22 weeks	54/75	72.0	202/301	67.1
23 weeks or older	40/69	58	211/350	60.3
χ^2 test for trend	p > 0.5		p < 0.001	
Test for departure from linearity	NA		p > 0.1	
Mantel-Haenszel		p > 0.9		
Socioeconomic status	n	%	n	%
V or never employed	57/70	81.4	77/93	82.8
III or IV	134/198	67.7	541/760	71.2
I or II	26/49	53.1	256/443	57.8
χ^2 test for trend	p < 0.001		p < 0.001	
Test for departure from linearity	p > 0.90		0.75 > p > 0.50	
Mantel-Haenszel		p > 0.90		
*Duration of breast feeding***	n	%	n	%
Never attempted	130/181	71.8	413/524	78.8
1–2 weeks	29/41	70.7	128/169	75.7
3–6 weeks	28/41	68.3	129/189	68.3
7–12 weeks	17/30	56.7	121/204	59.3
More than 12 weeks	13/25	52.0	86/212	40.6
χ^2 test for trend	p < 0.025		p < 0.001	
Test for departure from linearity	0.50 > p > 0.25		p < 0.01***	
Mantel-Haenszel		p > 0.10		
Maternal smoking	n	%	n	%
Does not smoke	62/103	60.2	597/931	64.1
1–9 cigarettes	60/86	69.8	119/158	75.3
10–19 cigarettes	52/70	74.3	106/142	74.6
20 or more cigarettes	43/59	72.9	54/66	81.8
χ^2 test for trend	0.10 > p > 0.05		p < 0.001	
Test for departure from linearity	NA		0.10 > p > 0.05	
Mantel-Haenszel		0.25 > p > 0.10		

Maternal smoking refers to smoking after pregnancy.
*Using approximate 25th, 50th, and 75th centiles of whole data set as a cut off.
**Using approximate 25th, 50th, and 75th centiles of all breast feeders as a cut off.
***When quadratic transformation was fitted p > 0.25.

infant age, socioeconomic status, duration of breast feeding, and the number of cigarettes the mother smoked. The proportion of pacifier users among the control infants decreased with increasing age, but this was not as apparent among the SIDS infants, mainly because of the comparatively small proportion of pacifier users below 2 months of age. For both groups, the proportion of pacifier users was lower for infants of families with higher socioeconomic status and for infants who breast fed for longer periods. The proportion of pacifier users increased with the number of cigarettes the mother smoked after pregnancy among the controls, but this did not reach significance among the victims of SIDS. Comparing the index and control infants within each stratum

for potential confounding (using the Mantel-Haenszel test) the duration of breast feeding and the number of cigarettes smoked by the mother had the greatest effect, but neither reached significance.

PACIFIER USE FOR THE LAST/REFERENCE SLEEP
Given the relative infrequency of pacifier use by some of the habitual pacifier users, it would be expected that the proportion of infants using a pacifier for the last or reference sleep would be smaller than the proportion of infants who had ever used a pacifier. Table 3 confirms this, but also shows that significantly fewer victims of SIDS (40%) than control infants (51%) used a pacifier. In the large multivariate model this association was strengthened when controlling for other variables. Specifically, if we controlled pacifier use for socioeconomic status, duration of breast feeding, or maternal smoking each of these factors increased the strength of the association with pacifier use, both individually and collectively (OR, 0.46; 95% CI, 0.33 to 0.65).

Table 4 stratifies the proportion of infants who used a pacifier on the last/reference sleep for infant age, socioeconomic status, duration of breast feeding, and the number of cigarettes the mother smoked after pregnancy. As with routine pacifier use there was a negative correlation with increased duration of breast feeding and a positive correlation with increased maternal smoking and lower socioeconomic status. Although these trends were significant among both the victims of SIDS and the controls, testing within strata did not reveal any evidence of significant confounding. In contrast to the inverse relation between usual pacifier use and infant age (table 2), there was a positive relation between the proportion of users for the last/reference sleep and increasing age. Infants who had used a pacifier but did not do so for the last/reference sleep tended to be younger; over 60% of both the SIDS and control groups were < 3 months old.

COMPARISON OF ROUTINE PACIFIER USE WITH USE ON LAST/REFERENCE SLEEP
Table 5 shows that in the univariate model there was a significant risk associated with usually using a pacifier but not doing so for the last/reference sleep. In a bivariate model, controlling for social class, pacifier use remained significantly associated with a reduced risk of SIDS and the risk associated with

Table 3   Pacifier use for the last/reference sleep

	SIDS		Controls			Multivariate OR* (95% CI)
	n = 313	%	n = 1296	%	Univariate OR (95% CI)	
Did not use a pacifier	189	60.4	632	48.8	1.00 (reference group)	1.00 (reference group)
Used a pacifier	124	39.6	664	51.2	0.62 (0.46 to 0.83)	0.41 (0.22 to 0.77)

For multivariate analysis, the following factors were controlled for—maternal age, parity, gestational age, birthweight, multiple births, unemployment, maternal smoking during pregnancy, paternal smoking and drug use, daily postnatal exposure to tobacco smoke, previous episode of an apparent life threatening event, maternal anxiety over infant becoming too hot, breast feeding and factors relating to the last 24 hours including: put down in the prone or side position to sleep, where the infant slept, being found with head covered, use of pillow in the cot, recent maternal alcohol consumption, parental estimate of poor health, length of previous sleep, and change in routine affecting the infant.
CI, confidence interval; OR, odds ratio.

Table 4   Pacifier use for the last/reference sleep stratified by age, socioeconomic status, breast feeding duration, and maternal smoking after pregnancy

	Proportion of infants who used a pacifier for the last/reference sleep			
	SIDS		Controls	
Infant age*	n	%	n	%
0–8 weeks	24/85	28.2	134/292	45.9
9–14 weeks	35/85	41.2	173/354	48.9
15–22 weeks	35/75	46.7	162/301	53.8
23 weeks or older	30/68	44.1	195/349	55.9
χ^2 test for trend	p < 0.05		p < 0.001	
Test for departure from linearity	0.25 > p > 0.10		0.90 > p > 0.75	
Mantel-Haenszel		p < 0.001		
Socioeconomic status	n	%	n	%
V or never employed	34/67	50.7	61/92	66.3
III or IV	74/197	37.6	409/759	53.9
I or II	16/48	33.3	193/442	43.7
χ^2 test for trend	p < 0.05		p < 0.001	
Test for departure from linearity	0.50 > p > 0.25		0.90 > p > 0.75	
Mantel-Haenszel		p < 0.001		
Duration of breast feeding**	n	%	n	%
Never attempted	81/179	45.3	319/522	61.1
1–2 weeks	16/40	40.0	100/169	59.2
3–6 weeks	13/41	31.7	92/189	48.7
7–12 weeks	8/29	27.6	81/203	39.9
More than 12 weeks	6/24	25.0	71/212	33.5
χ^2 test for trend	p < 0.01		p < 0.001	
Test for departure from linearity	0.75 > p > 0.50		0.25 > p > 0.10	
Mantel-Haenszel		p < 0.001		
Maternal smoking	n	%	n	%
Does not smoke	33/103	32.0	450/929	48.4
1–9 cigarettes	30/85	35.3	76/157	48.4
10–19 cigarettes	38/70	54.3	94/144	65.3
20 or more cigarettes	23/55	41.8	44/65	67.7
χ^2 test for trend	p < 0.025		p < 0.001	
Test for departure from linearity	0.10 > p > 0.05		0.25 > p > 0.10	
Mantel-Haenszel		p < 0.001		

Maternal smoking referes to maternal smoking after pregnancy.
*Using approximate 25th, 50th, and 75th centiles of whole data set as a cut off.
**Using approximate 25th, 50th, and 75th centiles of all breast feeders as a cut off.

usually using a pacifier but not doing so for the last/reference sleep became non-significant. In the multivariate model controlling for all significant factors, odds ratios and confidence intervals were similar to those for the bivariate model. In this multivariate model, all those factors (such as maternal smoking, socioeconomic status, bottle feeding, and infant illness) shown in our previous study[1] to be significantly associated with pacifier use are included, and do not significantly affect the results of this analysis. Splitting the data into younger and older infants by dividing at the median age for the total SIDS group (those aged less than 101 days and those 101 days and older), pacifier use for the last/reference sleep remained significant in both the univariate and the bivariate models,

Key messages
- There was no difference between victims of SIDS and control infants in routine use of a pacifier ("dummy" or "soother") for day or night sleeps
- The use of a pacifier was associated with a lower prevalence and shorter duration of breast feeding, lower socioeconomic status, and mothers who smoked more heavily
- There was no association between pacifier use and sleeping position
- More control infants used a pacifier for the last/reference sleep, giving an apparent "protective" effect against SIDS; the significance of this association increased when controlled for other factors
- Further epidemiological evidence and physiological studies are needed before we can recommend pacifier use as protective against SIDS

indicating that pacifier use was not an age dependent variable in the models.

PACIFIER USE ON LAST/REFERENCE SLEEP AND SLEEPING POSITION

Similar proportions were put down prone among infants who used a pacifier (13.9% SIDS group and 2.7% controls) or did not use one for the last/reference sleep (15.7% SIDS group and 3.3% controls). Similar proportions were also found in the prone position among infants who used a pacifier (39.3% SIDS group and 7.0% controls) or did not use one for the last/reference sleep (36.7% SIDS group and 5.3% controls).

Discussion

The similarity between the proportion of victims of SIDS and control infants reported as sometimes using a pacifier, and the similarity between this figure (68%) and that found in our prospective population study (65%) suggests that there was no systematic underreporting of pacifier use by parents of victims of SIDS.[1]

Our study confirms that there is an association between pacifier use and a reduced risk of SIDS. In addition, our study confirms the previously reported associations between pacifier use and infant feeding practices, parental

Table 5   Comparison of routine pacifier use and use for the last/reference sleep

		SIDS		Controls				
Ever used a pacifier	Pacifier for last sleep	n = 313	%	n = 1296	%	Univariate OR (95% CI)	Bivariate OR (95% CI)	Multivariate OR (95% CI)
No	No	95	30.4	386	29.8	1.00 (reference group)	1.00 (reference group)	1.00 (reference group)
Yes	No	94	30.0	246	19.0	1.55 (1.11 to 2.18)	1.39 (0.93 to 2.07)	1.22 (0.54 to 2.74)
No	Yes	5	1.6	36	2.8	0.56 (0.17 to 1.50)	0.37 (0.10 to 1.20)	0.65 (0.06 to 7.34)
Yes	Yes	119	38.0	628	48.5	0.77 (0.57 to 1.05)	0.63 (0.44 to 0.91)	0.44 (0.21 to 0.94)

In bivariate analysis occupational classification was controlled for.
In multivariate analysis the following factors were controlled for: maternal age, parity, gestational age, birth weight, multiple births, unemployment, maternal smoking during pregnancy, paternal smoking and drug use, daily postnatal exposure to tobacco smoke, previous episode of an apparent life threatening event, maternal anxiety over infant becoming too hot, breast feeding and factors relating to the last 24 hours including: put down in the prone or side position to sleep, where the infant slept, being found with head covered, use of pillow in the cot, recent maternal alcohol consumption, parental estimate of poor health, length of previous sleep, and change in routine affecting the infant.
CI, confidence interval; OR, odds ratio.

smoking, and socioeconomic status, but controlling for these and other relevant factors (such as prone sleeping position) in a multivariate analysis strengthened the apparent protective effect associated with pacifier use. These observations, together with the unique size and the comprehensive nature of the data collected in the CESDI/SUDI study, suggest that the protective association is real.

The observations on pacifier use from New Zealand[2] preceded the "back to sleep" campaign, yet found a magnitude of effect in a multivariate analysis (OR, 0.44; 95% CI, 0.26 to 0.73) that was very similar to ours (OR, 0.44; 95% CI, 0.21 to 0.94). In common with our study, the Dutch study[3] took place after the change in recommendations on sleeping position and found an even stronger univariate association (OR, 0.06; 95% CI, 0.01 to 0.25). A recommendation derived from this study, to use a pacifier, has been widely publicised in Holland, despite serious reservations expressed by Righard.[12] A study of routine pacifier use from Norway[4] found a large difference in routine use between SIDS infants (10%) and age matched controls (24%). Thus, four studies from different countries have shown associations between pacifier use and a reduced risk of SIDS.

It is important to emphasise that the association does not necessarily imply that the use of a pacifier is "protective" against SIDS, although the finding is compatible with this hypothesis. Even with a large and careful case control study, we cannot be sure that parents of victims of SIDS who use a pacifier are not systematically different in some unmeasured way from the controls. The possibility remains that the use of a pacifier may be confounded with some other factor of parental behaviour that has not been identified by the questionnaire but which is the reason for apparent risk reduction. Although pacifier sucking has been shown to increase oxygen tensions in preterm infants,[13] there are no published physiological data that identify a mechanism by which pacifiers might protect against SIDS, and no evidence in the epidemiological studies for a "dose response" effect of pacifier use.

Unless or until other corroborative evidence becomes available, it follows that health professionals should be cautious in recommending routine pacifier use on the grounds of protection against SIDS. The evidence for recommending that all babies should be given pacifiers to reduce the incidence of SIDS is weak—level III at best (US Agency for Health Care Policy and Research). Advice that is given routinely about the care of healthy babies must have at least as strong an evidence base as the treatment of those babies who are ill, because healthy babies are far more common, and the potential for unsuspected harm is relatively great, a lesson already bitterly learned for infant sleeping position.

It is widely believed that pacifiers have negative effects upon breast feeding, but few studies have considered this conflict in their conclusions, since pacifier use has been associated with both a decrease[14 15] and no effect[16] on the prevalence and duration of breast feeding. In our study there was a clear association between pacifier use and lower prevalence, as well as shorter duration of breast feeding, a finding compatible with a negative effect of pacifier use on breast feeding.

Pacifier use is associated with an increased incidence of respiratory and gastrointestinal illness.[1] That this association may be causal is plausible, given the difficulties of maintaining pacifiers in a hygienic state. There is little hard evidence for other widely held beliefs about harmful effects of pacifiers on tooth growth, palatal anatomy, or speech development.

The association between pacifier use and a reduced incidence of SIDS needs to be explored further because of the implications for infant care practices if evidence for a causal link should become strong. This will require knowledge of the physiological effects of pacifier use, awake and during sleep, in health and disease; further epidemiological studies to explore risk factors not identified in the existing studies; and a full evaluation of potential harm as well as potential benefit. No recommendations on pacifier use can be made in the light of present knowledge.

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